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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/025,363	02/18/98	MARK D	P97.1036

HM12/1223

HILL & SIMPSON
85TH FLOOR SEARS TOWER
233 SOUTH WACKER DRIVE
CHICAGO IL 60606

EXAMINER	
SHARAREH,S	
ART UNIT	**PAPER NUMBER**
1616	9

DATE MAILED: 12/23/99

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Advisory Action

Application No.	Applicant(s)
09/025,363	David Mark et al
Examiner	**Group Art Unit**
Shahnam Sharareh	1616

THE PERIOD FOR RESPONSE: [check only a) or b)]

a) ☐ expires _____ months from the mailing date of the final rejection.

b) ☒ expires either three months from the mailing date of the final rejection, or on the mailing date of this Advisory Action, whichever is later. In no event, however, will the statutory period for the response expire later than six months from the date of the final rejection.

Any extension of time must be obtained by filing a petition under 37 CFR 1.136(a), the proposed response and the appropriate fee. The date on which the response, the petition, and the fee have been filed is the date of the response and also the date for the purposes of determining the period of extension and the corresponding amount of the fee. Any extension fee pursuant to 37 CFR 1.17 will be calculated from the date of the originally set shortened statutory period for response or as set forth in b) above.

☐ Appellant's Brief is due two months from the date of the Notice of Appeal filed on _____ (or within any period for response set forth above, whichever is later). See 37 CFR 1.191(d) and 37 CFR 1.192(a).

Applicant's response to the final rejection, filed on *Sep 14, 1999* **has been considered with the following effect, but is NOT deemed to place the application in condition for allowance:**

☐ The proposed amendment(s):

☐ will be entered upon filing of a Notice of Appeal and an Appeal Brief.

☐ will not be entered because:

☐ they raise new issues that would require further consideration and/or search. (See note below).

☐ they raise the issue of new matter. (See note below).

☐ they are not deemed to place the application in better form for appeal by materially reducing or simplifying the issues for appeal.

☐ they present additional claims without cancelling a corresponding number of finally rejected claims.

NOTE: _____

☐ Applicant's response has overcome the following rejection(s):

_____

☐ Newly proposed or amended claims _____ would be allowable if submitted in a separate, timely filed amendment cancelling the non-allowable claims.

☒ The affidavit, exhibit or request for reconsideration has been considered but does NOT place the application in condition for allowance because: SEE ATTACHMENT

☐ The affidavit or exhibit will NOT be considered because it is not directed SOLELY to issues which were newly raised by the Examiner in the final rejection.

☒ For purposes of Appeal, the status of the claims is as follows (see attached written explanation, if any):

Claims allowed: _____

Claims objected to: _____

Claims rejected: *1-20*

☐ The proposed drawing correction filed on _____ ☐ has ☐ has not been approved by the Examiner.

☒ Note the attached Information Disclosure Statement(s), PTO-1449, Paper No(s). *7* .

☒ Other *see attached for response to arguements.*

Attachment to the Advisory Action

Claims 1-20 are pending.

Response to Applicants Arguments for Claim Rejections - 35 USC § 102

Applicant's arguments and the newly amended claims filed on December 3, 1999 have been fully considered but they are not found to be persuasive.

In contrary to Applicant's assertion that Schmidl et al does not anticipate the claimed invention, Examiner responds that Schmidl et al disclose suitable protein source including partially hydrolyzed protein (see col 4, lines 55-59.) and indicate the use of partially hydrolyzed protein or intact protein as the source of protein, not partially hydrolyzed protein and intact protein (see col 11 lines 31-34.) Further Schmidl's composition provides a non-protein calorie to grams of nitrogen ratio of ranging from 150:1 to 80:1 (see Col 5 lines 64-68 and Col 6 lines 1-11.) Applicant's argument that Schmidl's composition has caloric density of 1 Kcal/ml; not 1.4, is not impressive, because it inherently possess the claimed property. Schmidl et al disclose that their composition in the powder form has the caloric density of 4 cal/gram which can easily be diluted with an aqueous liquid or juice to yield the caloric density of 1.4 kcal/ml, while maintaining an osmolality of about 630-690 mosm/kg of water (see col 7 lines 50-59.) Thus, the rejection is proper and adhered to.

Response to Applicants Arguments for Claim Rejections - 35 USC § 103

Applicant's arguments and the newly amended claims filed on December 3, 1999 have been fully considered. Accordingly the rejections made under 35 USC § 103 in Paper no. 4, filed

on April 28, 1999 have been withdrawn. However, Applicant's arguments were not found persuasive in respect to the rejections made under 35 USC § 103 in Paper no. 6, filed on September 14, 1999 as being unpatentable over Schmidl et al US Patent 5,504,072 and Gray et al 5,714,472. In response to Applicant's argument Examiner replies that the test for obviousness is not whether the features of a secondary reference may be bodily incorporated into the structure of the primary reference; nor is it that the claimed invention must be expressly suggested in any one or all of the references. Rather, the test is what the combined teachings of the references would have suggested to those of ordinary skill in the art. See *In re Keller*, 642 F.2d 413, 208 USPQ 871 (CCPA 1981). In the instant case, Schmidl et al teach the desired NPC:N ratio for critically ill patients to be in the range of 150:1 to 80:1 (see col 5 lines 65-67 and col 6 lines 1-3.) further it is well known in the art that the nitrogen content of the composition can be measured to best fit the needs of critically ill patients; as indicated by Schmidl et al (see col 6 lines 2-9.) Also the use of antioxidants, vitamins and various minerals is routine in nutrition art, and further Schmidl et al provide such teachings in their patent (see col 9 lines 45-66, col 10 lines 1-25.)

Gray et al teach an enteral nutritional formulation that meets the nutritional needs of critically ill and metabolically stressed patients such as post-surgical patients or patients suffering from trauma in an intensive care setting, therefore, one skilled artisan would have been motivated to change the nonprotein calorie to grams of nitrogen ratio of Gray's composition to the desired ratio best fit for critically ill patients; as taught by Schmidl et al, and modify Gray's composition to formulate a product that suit the needs of metabolically stressed patients.

For the above stated reasons, said claims are properly rejected under 35 U.S.C § 103, and therefore, the rejections are adhered to.

In response to Applicant's arguments that the amended claims in Paper No. 5, filed on July 19, 1999 did not necessitate the new ground of rejection, Examiner replies that the amended claims clearly change the scope of the original independent claims, thus Applicant's amendment necessitated new grounds of rejection and accordingly the action was made final. See MPEP 706.07(a).

All rejections that were not addressed in the final rejection are considered moot.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Shahnam Sharareh, PharmD whose telephone number is (703) 306-5400.

sjs 12/21/99

JOSE G. DEES
SUPERVISORY PATENT EXAMINER
1616